

## **REMARKS**

Reconsideration and withdrawal of all rejections of the application, and allowance of the claims, especially in view of the remarks herein, are respectfully requested, as this paper places the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

The herein amendments to the specification address the objections to the specification and the abstract. The specification amendments includes no new matter.

Claims 28-31 were under consideration. Claims 38-31 are canceled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. New claims 32 to 34 have been added. No new matter has been added.

Support the new claims is found throughout the specification, for example, paragraphs 15, 16, 17, 28 and 61 of the specification as published and in the claims as originally filed.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE OBJECTIONS TO THE SPECIFICATION ARE OVERCOME**

The Office Action objected to the Abstract because the first sentence is incomplete due to a typographical error. In response, Applicants amend the Abstract to correct the typographical error.

Furthermore, the Office Action maintained the objection to the specification, as the recitation of the term “paragraph” is allegedly confusing since it is unclear which paragraph is being referred. In response, Applicants inserted paragraph breaks and refer back to the numbered paragraphs in the specification.

In view of the above amendments, reconsideration and withdrawal of the objections to the abstract is respectfully requested.

### **III. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

#### **A. Written Description**

Claims 28-29 and 31 are rejected under 35 U.S.C. §112, first paragraph, allegedly failing to satisfy the written description requirement. The rejection is traversed.

According to the Office Action, the claims do not set forth the hybridization conditions that are considered to be stringent, as the art recognizes that hybridization conditions can vary. In addition, the Office Action contends a sequence which hybridizes to the sequence of interest may not necessarily encode the same protein. Furthermore, the Office Action alleges that the claims encompass a genus of variant DNA sequences, although representative species of the genus has not been adequately described.

In response, Applicants draw attention to the amendment to the claims. Notably, claim 32 herein clarifies the stringent conditions as comprising hybridization at 65°C in a buffer containing 0.1x SSC. Additionally, claim 33 directs the subject matter to a DNA molecule encoding a protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, and SEQ ID NO: 6. Hence, the allegations related to the encoded protein comprising the amino acid sequence according to claim 28 is rendered moot.

Applicants further assert that the isolated DNA molecule of the instant claims was in possession of Applicants at the time of filing. This is evidenced by the sufficient description of the molecule in the specification, notably in the paragraphs beginning on page 6, lines 2 and 25, on page 10, line 6, and on page 11, line 15, and in Example 1.

Therefore, the amended claims presented herein satisfy the written description requirements of 35 U.S.C. §112, first paragraph.

#### **B. Enablement**

Claims 28-31 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to meet the enablement requirement. The rejection is traversed.

According to the Office Action, the specification does not provide enablement for DNA encoding proteins set forth by any variant of SEQ ID NOS: 2, 4, and 6. The Office Action contends that the amount of experimentation is undue since the claimed invention encompasses a large amount of variability for the DNA and the encoding protein sequence, and there is no correlation made between the structure and function of the claimed products. The skilled artisan

would allegedly have to screen the large number of variants that can be generated in order to determine which variants have the desired functional activity. The Office Action also alleges that it is unpredictable which changes in the amino acid sequence can be tolerated while obtaining the desired activity, and that there is no guidance or working examples related to which changes in structure will affect function. Finally, the Office Action contends that the claims are broad in scope since they encompass unspecified amount of fragments.

In response, Applicants argue that the amendments presented herein to claims 32-34 satisfy the enablement requirements of 35 U.S.C. §112, first paragraph. The new claims do not encompass a large amount of variability and are not broad in scope for the claimed DNA and amino acid sequences. Instead, the claim 33 encompass isolated DNA molecules that comprise (a) the sequence of SEQ ID NO: 1, or (b) the sequence of SEQ ID NO: 3, or (c) the sequence or SEQ ID NO: 5, or (d) the sequence of SEQ ID NO: 1, SEQ ID NO: 3 and SEQ ID NO: 5, or (e) a sequence that hybridizes with the full complement of the sequence in (a), (b), (c) or (d) under stringent conditions, wherein the variant sequence encodes a protein that binds to Filamin 1 and inhibits cell migration, and wherein the stringent conditions comprise hybridization at 65°C in a buffer containing 0.1x SSC.

Furthermore, subject matter related to the encoded protein as recited in claim 33 has been modified, wherein an isolated DNA molecule that encodes a protein, wherein the protein comprises the amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, and SEQ ID NO: 6. Notably, the Office Action concedes that the specification is “enabling for the DNA encoding proteins set forth in SEQ ID NOS: 2, 4, and 6” (see specification, page 7, lines 1-2).

The Office Action also asserts that undue experimentation would be required to practice the present invention. Applicants respectfully disagree. It would not require undue experimentation for one of skill in the art to practice the invention using FILIP variants having the physical and functional properties recited in the new claims.

The level of skill in the art of molecular neuroscience is high, and was high at the time when the present application was filed. For example, it would have been well known to one skilled in the art at the time of the invention, how to determine if a given nucleotide sequence hybridizes with the full complement of the sequence in (a) the sequence of SEQ ID NO: 1, or (b) the sequence of SEQ ID NO: 3, or (c) the sequence or SEQ ID NO: 5, or (d) the sequence of

SEQ ID NO: 1, SEQ ID NO: 3 and SEQ ID NO: 5 under stringent conditions, wherein the variant sequence encodes a protein that binds to Filamin 1 and inhibits cell migration, and wherein the stringent conditions comprise hybridization at 65°C in a buffer containing 0.1x SSC. disclosed in the claims. Moreover, the specification of the present application provides considerable guidance as to how to test whether a given variant protein has the recited features. For example, the specification teaches how to determine whether a given protein binds to Filamin-1 using the yeast two-hybrid assay, how to determine whether a given protein binds to Filamin-1 using immuno-precipitation assays, and how to determine whether a given protein co-localizes with Filamin-1 using immunocytochemistry. (See Example 2, starting on page 34 of the specification). All of these assays are routinely practiced by those skilled in the art, and do not require undue experimentation. The specification also describes how to determine whether FILIP proteins or FILIP variant proteins, have an effect on cell migration by teaching how to determine cell migration rate in FILIP-transfected cells, and how to measure lamellipodium formation (correlated with cell migration ability) using *in vitro* wound healing assays. These assays are also routinely practiced by those skilled in the art and do not require undue experimentation.

Accordingly, in view of the above remarks, it is clear that the instant claims fulfill the enablement requirement. The scope of the claims is not broad in view of the amendments herein, and the specification provides ample guidance and working examples to enable a skilled artisan to practice the present invention without undue experimentation.

Reconsideration and withdrawal of the rejections of the claims under 35 U.S.C § 112, first paragraph, is respectfully requested.

#### **IV. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

The Examiner has rejected claims 28-31 under 35 U.S.C. §112, second paragraph, for allegedly failing to set forth the subject matter which the applicant(s) regard as their invention. This rejection is traversed.

The Office Action asserts that claim 28 is indefinite because it recites to “stringent hybridization conditions” without setting forth what conditions are deemed to be stringent, thereby leaving the metes and bounds of the claim undefined.

In response, Applicants note claim 32, wherein the stringent conditions are clarified as comprising hybridization at 65°C in a buffer containing 0.1x SSC. Consequently, instant claim 32 sufficiently defines the stringent condition; accordingly, reconsideration and withdrawal of the rejections of the rejection under 35 U.S.C § 112, first paragraph, is respectfully requested.

**V. REJECTIONS UNDER 35 U.S.C. §102(b)**

Claims 28, 29, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Dyson et al. (J Cell Biol 155: 1065-1079, 2001). The rejection is traversed.

The Office Action considers the broadest interpretation of claims 28 and 29 as a sequence that binds filamin, as these claims allegedly require very little structure with the functional limitation. The Office Action further asserts that Dyson et al. disclose a DNA encoding a protein which binds filamin, thus reading on the claims.

Claims 32 to 34 as presented herein are not anticipated by Dyson et al. In contrast, Dyson et al. relates to a phosphoinositidylinositol 3,4,5 triphosphate 5-phosphatase, SHIP-2, because SHIP-2. SHIP-2 binds filamin; however Dyson et al. does not teach the stringent conditions described in claim 28. Notably, claim 30, which formerly disclosed the stringent conditions, was not considered anticipated by Dyson. Further, Dyson does not teach the sequences disclosed in claim 32.

As such, Dyson does not anticipate claims 32 to 34. Accordingly, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §102(b) is respectfully requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the remarks and amendments, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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